



THIS ISSUE

Recent Medical Coverage Decisions on Intradiscal Heating (IDET) and Vertebral Axial Decompression Therapy (Vax-D)

TO:

Ambulatory Surgery Centers
Anesthesiologists
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Purpose:

The purpose of this bulletin is to notify providers about recent medical coverage decisions pertaining to Intradiscal Heating and Vertebral Axial Decompression Therapy (Vax-D). These coverage decisions are applicable to both State Fund and Self-Insured claims and are currently in effect. A brief description of the procedure-(s) and coverage decision rationale is included. The criteria used for medical coverage decisions are also summarized.

Intradiscal Heating

Intradiscal heating consists of inserting a needle or catheter into an intervertebral disc space to deliver controlled heat for treatment of discogenic pain. Shrinkage of collagen fibers, cauterization of granulation tissue, and thermocoagulation of nervous tissue results. There are two methods currently employed to deliver heat to a herniated disc: radiofrequency generated heat and heat generated by a resistive coil at the tip of a catheter.

These methods are supposed to be used in conjunction with safety parameters so that they do not lead to permanent tissue damage. Residual fibroblasts are left intact so that they repair the tissue by replacing denatured collagen with new collagen. The desired outcome of intradiscal heating is to achieve tissue shrinkage, which is maintained as the tissue heals and regains its mechanical properties.

Currently, no randomly controlled clinical trials have been published in peer-reviewed journals on electrothermal or radiofrequency controlled intradiscal heating. For a complete copy of the technology assessment/literature review done on intradiscal heating by the department, call Troy Parks at (360) 902-6324.

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Radiofrequency generated technique

The earliest method was developed in the early 1990's and employs radiofrequency (RF) generated heat. Radiofrequency controlled delivery systems include the straight needle delivery method, a technique shown to be more promising on shoulders than on discs because exact placement is difficult. This technique is criticized primarily because of the lack of ability of the RF current to effectively reach therapeutic temperatures in the surrounding tissue. It is speculated that the effective heating radius is probably limited to 2 to 4 mm distances from the needle tip.

Intradiscal Electrothermal Treatment (IDET)

The newer method of intradiscal heating, marketed as Oratec's SpineCath, employs electrically generated heat through a thermal resistive coil with a navigable hooked catheter. With IDET, also known as intradiscal electrothermal treatment or annuloplasty, heat is delivered at a recommended temperature of 65 Celsius to the disc nucleus and annular wall via the rounded catheter, for approximately 15 minutes.

Some practitioners report that optimal catheter placement is the outer posterior third of the disc, across the midline of the posterior wall and centered between the end plates. This technique differs from radiofrequency, where heat generated by cannulae dissipates into the disc.

Oratec's SpineCath, substantially equivalent to a device marketed in interstate commerce prior to May 28, 1976, received 510-(k) pre-market clearance from the Food and Drug Administration (FDA) on March 19, 1998. Clinical performance data is generally not required to obtain pre-market clearance for products determined to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, and was not submitted in support of Oratec's 510(K) application.

Coverage Decision

At this time, the department does **not** cover intradiscal heating techniques. There is not substantial scientific evidence documenting the long term safety and efficacy of intradiscal heating, particularly in the injured worker population.

Vertebral Axial Decompression (Vax-D)

Vax-D is an air-powered auto-traction table, split down the middle, which applies cycles of tension axially to the lumbar vertebral column. The table is designed to create lumbar vertebral body separation, which is said to unload the spine through decompression of the nucleus pulposii. A pelvic harness is attached to the lower body of the patient who lays prone on the Vax-D table. The patient grips handholds on the upper part of the table. The table separates in two, applying traction to the spine. An attached tensionometer delivers precisely controlled cycles of distraction and relaxation. The patient can stop the movement of the table by releasing the handgrips, which stops the tension immediately. The FDA cleared Vax-D for marketing in 1989 as a powered traction device. The device is substantially equivalent to a pelvic traction table called Vax-T, which was marketed by the same company.

Coverage Decision

When traction is a proper and necessary treatment for a worker, the department or self-insured employer may pay for traction therapy administered by a licensed physical therapist or physiatrist using Vax-D only to the same extent it would pay for traction therapy using other approved traction devices. See Washington Administrative Code (WAC) 296-20-01002 for a complete definition of "proper and necessary" medical services.

The benefits of traction in general are not well documented. In its 1994 publication, “*Low Back Pain in Adults*” the U.S. Agency for Health Care Policy and Research did not recommend spinal traction in the treatment of patients with acute low back pain.¹

The department is unable to establish whether or not Vax-D is more effective than other similar forms of traction on the market. There have been no controlled studies comparing Vax-D with other types of traction, surgery or any other treatment.

Billing

The department **will not pay an additional cost** when this device is used. For billing and payment purposes, CPT 97012 is used for the provision of traction therapy. Only one unit of this code may be billed per visit, regardless of the length of time traction is applied.

Physical Medicine and Physical Therapy Payment Policies

For a complete description of our physical medicine and physical therapy payment policies, please refer to the “Physical Medicine” and “Physical and Occupational Therapy” sections of the “Washington RBRVS Payment Policies” section of the *Medical Aid Rules and Fee Schedules*. The rules and regulations for physicians providing physical medicine services can be found in WAC 296-21-290. For rules and regulations for physical therapists, see WAC 296-23-220.

Criteria for Medical Coverage Decisions

Washington Administrative Code (WAC) 296-20-02704 outlines the criteria the department uses to make medical coverage decisions. Provider Bulletin 00-01 includes a full text of this WAC. In summary: A medical coverage decision is a general policy decision by the director or the director’s designee to include or exclude a specific health care service or supply as a covered benefit. These decisions are made to ensure quality of care and prompt treatment of workers.

Medical coverage decisions include, but are not limited to, decisions on health care services and supplies rendered for the purpose of diagnosis, treatment or prognosis. In making medical coverage decisions, the director or the director’s designee considers information from a variety of sources. These sources include, but are not limited to:

- Scientific evidence;
- National and community-based opinions;
- Informal syntheses of provider opinion;
- Experience of the department and other entities;
- Regulatory status.

Reconsideration of Medical Coverage Decisions

Medical coverage decisions are not permanent. Additional substantive data in those criteria listed above, particularly newly published findings from clinical studies documenting the long term safety and efficacy of a health care service or supply, will be used to re-examine medical coverage decisions.

¹ U.S. Department of Health and Human Services, Agency for Health Care Policy and Research. *Clinical Practice Guideline #14: Acute Low Back Problems in Adults. December 1994.*

For reconsideration of medical coverage decisions (i.e. general policy decisions about covered benefits) please contact the Office of the Medical Director at:

Department of Labor and Industries
Office of the Medical Director
P.O. Box 44321
Olympia, WA 98504-4321

Exceptions to Medical Coverage Decisions on Individual Claims

The department or self-insurer will not generally authorize or pay for treatment measures of a controversial, obsolete, investigational, or experimental nature (WAC 296-30-03002). Under certain conditions, however, the director or the director's designee may determine that such treatment is appropriate. In making such a decision, the director or director's designee will consider factors including, but not limited to, the following:

- (a) Scientific studies investigating the safety and efficacy of the treatment are incomplete, or if completed, have conflicting conclusions, and:
 - Preliminary data indicate the treatment or diagnostic procedure or device has improved net health and functional outcomes; and
 - No alternative treatment or diagnostic is available; or
- (b) The treatment or diagnostic procedure or device is prescribed as part of a controlled, clinical trial; or
- (c) The usually indicated procedure or diagnostic test would likely be harmful for the patient because of other unrelated conditions.

The health care provider must submit a written request and obtain approval from the department or self-insurer, prior to using a controversial, obsolete, investigational, or experimental treatment. The written requests must contain a description of the treatment, the reason for the request, potential risks and expected benefits, length of care and estimated cost of treatment.

Where is more information available?

The Provider Hot Line @ 1-800-848-0811

Hot line can help you with:

- Billing questions
- Clarification of Provider Bulletins, fee schedules, department policies, WACs, and RCWs
- Authorizations

Providers can also call the department's **Interactive Voice Response (IVR)** system at 1-800-831-5227 between the hours of 6:00am and 7:00pm weekdays, to obtain automated information regarding the status of a claim, authorized medical procedures, allowed diagnosis, a claim manager's name and phone number, and other claim specific information.

Office of the Medical Director

For additional information on existing medical coverage decisions or if you have a question about a new emerging technology, device, or off-label use of a drug, contact the Office of the Medical Director at:

Department of Labor and Industries
Office of the Medical Director
P.O. Box 44321
Olympia, WA 98504-4321

For questions about what will be authorized on a specific claim, contact the self-insured employer or State Fund claim manager.

The Office of the Medical Director website is located at <http://www.lni.wa.gov/omd/>

This website features:

- Diagnosis and treatment guidelines
- Health links
- Department health policies
- Department-sponsored medical publications
- Recent medical coverage decisions

Health Services Analysis Website is located at <http://www.lni.wa.gov/hsa/>

This website features:

- Provider Bulletins and Provider Updates
- Medical Aid Rules and Fee Schedules
- Provider education opportunities
- Provider authorization information
- Provider patient information